



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )

Jong-Soo Woo et al. )

Serial No.: 10/660,859 )

Filed: September 12, 2003 )

Group Art Unit: 1617

Examiner: CLAYTOR, DEIRDRE  
RENEE

For: ORAL ITRACONAZOLE COMPOSITION)

WHICH IS NOT AFFECTED BY )

INGESTED FOOD AND PROCESS FOR)

PREPARING SAME )

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. SECTION 1.132

I, Jong-Soo WOO, being a citizen of the Republic of Korea and presently residing at Daewolmaeul 821-105, #914, Jeongja-dong, Jangan-gu, Suwon-si, Kyungki-do 440-300, Republic of Korea, do declare:

That I am one of the co-inventors of the invention disclosed in the above-identified application, and hence am fully familiar with the subject matter therein; and

That I have conducted a comparative experiment (*in vivo* absorption test on twenty 19 to 55 year-old healthy adults) based on Test Example 2 of the specification as originally filed by using the inventive preparation of Example 1 and Sporanox<sup>®</sup> tablet to demonstrate the

		AUC <sup>*1</sup> (ng·hr/mL)	C <sub>max</sub> <sup>*2</sup> (ng/mL)	AUC <sub>before ingestion</sub> /AUC <sub>after ingestion</sub> (%)
Inventive preparation	Before ingestion	1747.00	307.49	92%
	After ingestion	1890.21	264.48	
Sporanox <sup>®</sup> tablet	Before ingestion	232.75	42.94	47%
	After ingestion	497.50	82.39	

\*1 Area under the curve of blood concentration till 48 hours

\*2 Maximum blood concentration

As can be seen from the above results, it can be concluded that bioavailability of itraconazole observed for the inventive preparation is higher and far less adversely affected by ingested food as compared to that of Sporanox<sup>®</sup> tablet.

The undersigned declarant further declares that all statement made therein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Dated: January 15, 2007

By: J. S. Woo  
Jong-Soo WOO